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요추간판성 신경근병증에 대한 수핵성형술 적용의 해부학적 고찰

조선대학교 대학원

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An anatomical study on the application of nucleoplasty for lumbar discogenic radiculopathy

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국문 초록

요추간판성 신경근병증에 대한 수핵성형술 적용의 해부학적 고찰

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목적. 요추간판성 신경근병증을 수핵성형술로 치료할 때, 임상 결과에 영향을 미치는 해부학적 요인들을 연구하고자 한다.

방법. 2018년 6월부터 2019년 9월까지 추간판탈출로 발생한 요추 추간판성 신경근병증에 대해 수핵성형술을 시행한 57 명의 환자가 포함되었다. 환자들의 특성과 임상 결과는 의무 기록에서 얻었다. 수술 전후 숫자통증등급(Numeric rating scale; NRS)의 차이로 통증 개선정도를 수집하였고, MacNab 기준을 이용하여 환자 만족도에 대한 데이터를 수집하였다. 임상 결과에 영향을 미칠 수 있는 해부학적 요소로는 탈출된 추간판의 레벨, 탈출된 추간판의 너비, 척추 협착증 동반 여부, 골극 동반 여부, 추간판의 높이, 추간판의 퇴행성 정도, 진공 추간판 여부, 자기공명영상에서 관찰되는 탈출된 추간판 부위의 성상에 대한 데이터를 수집하였다. 수집된 해부학적 요소들과 임상 결과에 대한 데이터를 토대로, 통계학적 분석을 통해 종합적으로 상관관계를 조사하였다.

결과. 전체 환자에서 수술 전 및 수술 후 하지방사통의 평균 NRS 점수는 각각 6.70 ± 1.26 (범위 3부터 9) 및 4.05 ± 2.19 (범위 0부터 8)였다. NRS 점수의 평균 감소는 2.64 ± 2.28 (범위 0부터 8)이었다. MacNab 기준에 대

한 환자 만족도는 다음과 같이 밝혀졌다: 10명(17.5%)의 환자는 '탁월(excellent)' 했고, 16명(28.1%)의 환자는 '우수(good)'했고, 14명(24.6%)의 환자는 '보통(fair)'이었고, 17명(29.8 %)의 환자는 '불량(poor)'이었다. 탈출된 추간판의 레벨, 탈출된 추간판의 너비, 척추 협착증 동반 여부, 골극 동반 여부, 추간판의 높이, 진공 추간판 여부, 자기공명영상 상 관찰되는 탈출된 부위의 물리적 성상은 임상 결과에 유의한 차이를 만드는 요인이 아니라는 것이 통계적으로 밝혀졌다. 그러나 Pfirrmann 등급 시스템에 의해 등급 II 또는 III에 속하는 추간판은 등급 IV 또는 V보다 NRS 감소율이 상당히 높았고 (54.9 % 대 21.7 %; p = 0.016), MacNab 기준이 더 우수했다 (p = 0.02). 압출된 형태(extrusion type)의 추간판 탈출증은 돌출된 형태(protrusion type)의 그것보다 NRS 감소율이 상당히 높았다 (67.3 % 대 34.3 %; p = 0.009). 그러나 MacNab 기준은 통계적으로 유의한 차이를 보이지 않았다 (p = 0.065). Pfirrmann 등급이 II 또는 III에 속하면서 동시에 압출된 형태의 추간판 탈출증이 있었던 환자군은 총 여덟명이었으며, NRS 감소율이 67.9% 였으며, 그 중 여섯은 만족도 설문에 MacNab 기준 상 '탁월'에 해당한다고 답했다.

결론. 추간판 탈출증으로 인한 요추 추간판성 신경근병증에 대해 수핵성형술 치료는 특정 해부학적 조건에서만 효과적일 수 있다. Pfirrmann 등급 III 보다 심한 퇴행성 추간판 변성이 있는 요추 추간판성 신경근병증은 수핵성형술의 적응증에서 제외되어야 한다. 일반적인 통념과는 달리 압출된 형태(extrusion type)의 추간판 탈출증은 효과적인 기술이 적용된다면 수핵성형술에 대한 적응증 범위에 포함될 수 있다고 생각된다.

Key Words : Nucleoplasty, Lumbar Disc Herniation, Lumbar radiculopathy

I. Introduction

Lumbar discogenic radiculopathy (LDR) is one of the most common spinal disorders which can lead to high medical expenses for the patient, occupational impairment, and social problems such as isolation and loneliness. Neurosurgeons have been studying and trying to develop more effective techniques to manage LDR, and these techniques are evolving to pursue minimal invasiveness. A good example of this trend is nucleoplasty surgery using coblation technology. However, many surgeons are not interested in this technique. Some of them do not trust this novel way to treat discogenic pathologies and would not even consider it as a treatment option in their clinical practices. There have even been reports stating that nucleoplasty is not an effective treatment for lumbar disc pathology.[1] However, many other reports have been published which support the effectiveness of nucleoplasty for LDR, as well as discogenic lower back pain.[2-4] Nevertheless, there has been no detailed report researching what affects the clinical result by analysing various anatomical factors in the disc which need to be treated. Thus, the purpose of this study was to determine the anatomical factors which affect the clinical outcome in the treatment of LDR with nucleoplasty and to find out what makes nucleoplasty an effective therapy option for LDR. The study was conducted on patients with LDR, who were randomly selected and treated without considering other anatomical factors.

II. Materials and Methods

Prior to the beginning of this study, the Institutional Review Board's approval was obtained. From June 2018 to September 2019, 222 patients underwent nucleoplasty surgery for their lumbar disc pathologies by a single neurosurgeon. The patients' medical records and radiological images were all reviewed in order to sort subjects into the following inclusion criteria group: 1) having disc herniation in a single level, 2) contained disc herniation with no discontinuity of the annulus surrounding the displaced disc material, 3) having radiating leg pain and obviously corresponding lumbar disc herniation with root compression, 4) no other disc levels with the potential to cause radiating leg pain in the lumbar spine, 5) no other body lesion having the potential to cause leg pain, and 6) a follow-up period of at least 3 months after the procedure. The exclusion criteria were as follows: 1) broad based diffuse bulging type disc herniation, 2) uncontained disc herniation including cases having disc material migration or sequestration, 3) incomplete medical records, 4) discogenic axial pain without any evidence of lumbar radiculopathy in the medical records, and 5) an ambiguous correlation between leg pain and radiologic images.

The medical records of patients selected by these criteria were fully reviewed to obtain data such as age, gender, disease duration, post-operational complications, history of previous discectomy and clinical outcome. The clinical outcome was assessed by pre- and post-operational pain measurement in the numeric rating scale (NRS) and patient satisfaction was evaluated via the MacNab criteria. The MacNab criteria are used as an outcome assessment of patient satisfaction after treatment, and the grading is stepped as excellent, good, fair, and poor. In this study, both the excellent and good results are defined as "satisfied," and both the fair and poor results are

defined as "unsatisfied." The radiological images were all rigorously reviewed to identify anatomical factors which have the possibility to affect the clinical results. These included the level of disc herniation, the shape of the displaced disc material, the width of disc herniation, pre-existing spinal stenosis, accompanying osteophyte, disc height, the degree of disc degeneration, vacuum disc phenomenon, and the physiologic appearance of the displaced material in magnetic resonance imaging (MRI) (Fig. 1).

Based on the shape of the displaced disc material, it was classified as either protrusion or extrusion type. The diffuse bulging type was excluded from this study, because it is not clear if the bulged disc causes nerve root compression. Between the two types of herniation, the extrusion type is the more severe form in which the nucleus pulposus moves out of the disc space so that the greatest diameter of the displaced disc material is larger than the base at the disc space of origin.[5] The data on the width of disc herniation were gathered based on the division system of anatomic zone by Wiltse regarding location of disc fragments.[6] Using this system, all patients were divided into two groups, depending on whether the base of disc herniation was localized only in a single compartment or widely distributed in two or more compartments. The disc height was assessed by measuring the minimal gap between the upper and lower endplates in the sagittal plane of T2-weighted images (T2WI) on MRI. Pre-existing spinal stenosis does not matter when disc herniation is in the foraminal or extra-foraminal zone, and so only patients who had herniated disc material in the central zone or subarticular zone were included. The degree of disc degeneration was graded using the grading system by Pfirrmann.[7] The ones in grade II and III were defined as the mild to moderate degeneration group, and those in grade IV and V as the severe

degeneration group. If the preoperative MRI findings showed that the herniated nucleus pulposus was observed with low signal intensity in T2WI, suggesting dehydration and stiff condition, it was defined as a stiff herniation. The others are defined as soft disc herniations.

Based on all the collected data, the author used statistical analysis to investigate which anatomical factors affected the clinical results.

Surgical technique

The patients were laid on the surgical table in a prone position after receiving pre-operative antibiotics. A pillow was placed under the abdomen to flex the lumbar spine. After sterilization of the surgical site, the approaching trajectory and skin entry point was identified at 10-12 centimeters (cm) lateral from the midline on the low back under fluoroscopic guidance. A local anesthesia was applied via lidocaine injection from the skin to deep inside the lower back musculature, following the approach way. An introducer needle, with a diameter of 1.8 millimeters (mm) and length of 19 cm, was inserted into the disc space passing through Kambin's triangle. After placing the tip of the needle in the nucleus pulposus, the YES DISC ® (Mcare, Seongnam-si, Gyeonggi-do, South Korea) was engaged into the disc space through the introducer needle and the radio frequency probe of the device approached the herniated portion of the disc under fluoroscopic guidance. The plasma energy from the probe was applied to the target site and nearby area for approximately 10 minutes. The patients were discharged within a week and advised to rest for at least two weeks afterwards. Figure 2 shows the sequential process from skin entry of the introducer needle to approach of the radio frequency probe.

Statistical analysis

All data were analyzed using SPSS 25 software (SPSS Inc, Chicago, IL, USA). Differences in clinical outcomes were analyzed for all anatomical factors using the independent t-test, the Mann-Whitney U test, the Spearman's correlation, the Chi-squared test, the Fisher's exact test, and the Kruskal-Wallis test. $P<0.05$ was considered statistically significant in all analyses.

III. Results

Patient demographics

Out of a total of 222 patients who underwent nucleoplasty for lumbar disc pathology during the period of investigation, 57 patients met the criteria and were enrolled in this study, there were 33 males (57.9%) and 24 females (42.1%). The mean age of the population was 55.9±15.1 years (range 20 to 81 years). The mean duration of radiating pain was 8.2±13.9 months (range 1 to 60 months). The mean follow-up period was 9.4±4.3 months (range 3 to 18 months). Five patients had previously undergone discectomy on the same level of the treated disc. Because each patient was treated in single level disc, a total of 57 discs were involved in this study. Demographic data are shown in Table 1.

Anatomical factors in radiographs

The level distribution of the treated disc was as follows: L2-3 disc, one (1.8%); L3-4 disc, seven (12.3%); L4-5 disc, 30 (52.6%); and L5-S1 disc, 19 (33.3%). Twenty-three (40.4%) discs had herniations within a single zone, and 34 (59.6%) discs had broad based herniations over multiple zones. By shape classification of the displaced disc, 48 (84.2%) discs were the protrusion type and nine (15.8%) discs were the extrusion type. In 40 disc herniations the range of herniation included the central canal side. Out of all 57 patients, 10 (25%) patients had pre-existing spinal stenosis on their treated level, and 16 (28.1%) disc herniations were accompanied by an osteophyte. The mean value of disc height was 2.2±1.1 mm (range 0.4 to 5.1 mm). The degree of disc degeneration was graded using the system developed by Pfirrmann, and one (1.8%) disc was on grade II; 41 (71.9%) discs were on grade III; 10 (17.5%) discs were on grade IV; five (8.8%) discs were on grade V; and

there was no one on grade I. The physiologic appearance of the displaced material was assessed with T2WI on MRI, and 13 (22.8%) discs showed stiff herniation, while 44 (77.2%) were soft herniation type. Vacuum formation in the disc space was found in 12 (21.1%) discs.

Clinical outcomes

The mean NRS score pre-operatively, and at the last follow-up, for radiating leg pain in patients was 6.70±1.26 (range 3 to 9) and 4.05±2.19 (range 0 to 8), respectively. The mean reduction in NRS score was 2.64±2.28 (range 0 to 8). The assessment of patients' satisfaction following the Macnab criteria revealed as follows; 10 (17.5%) patients were on excellent, 16 (28.1%) patients were on good, 14 (24.6%) patients were on fair, and 17 (29.8%) patients were on poor. Fifteen patients had temporary dysesthesia of the leg on the side from which the needle approached after the procedure, but there were no major complications. Eight patients had undergone a second surgery elsewhere because their pain did not improve as much as desired.

Correlations between anatomical factors and clinical outcomes

Differences in clinical outcome, i.e. the mean NRS reduction rate (%) and the MacNab criteria, were analyzed in relation to all the anatomical factors, and the correlation data is summarized in Table 2.

It revealed that the level of disc herniation, the width of disc herniation, pre-existing spinal stenosis, accompanying osteophyte, disc height, the physiologic appearance of the displaced disc material, and the presence of vacuum disc did not have an effect on the clinical outcome. By evaluating the degree of disc degeneration, however, it revealed that discs which belong to grade II or III in the Pfirrmann grading system showed a significantly higher NRS reduction rate (54.9%

vs 21.7%; p=0.016) and better outcomes in the MacNab criteria (p=0.02) than those which were in grade IV or V. In terms of the shape of the displaced disc material, the extruded disc herniation showed a significantly higher NRS reduction rate (67.3% vs 34.3%; p=0.009), and better outcomes in the MacNab criteria (p=0.065) than protruded disc herniation, but it showed no significance.

IV. Discussion

The most important goal of surgical treatment for LDR is decompression of the affected nerve root. Nucleoplasty is essentially an intradiscal approach technique and its main effect is on the nucleus pulposus, it hardly has effect on the annulus. This leads to many neurosurgeons believing that the role of nucleoplasty in achieving neural decompression might be limited. Furthermore, Ogbonnaya et al. reported that symptom resolution of LDR by nucleoplasty was not significantly different, even when compared to the natural history of a herniated disc.[8] In contrast, there were also reports claiming that nucleoplasty was quite effective in treating LDR.[9] And some authors emphasized that proper patient selection is important.[10] However, no studies have analyzed in detail the multifarious anatomical factors of intervertebral disc lesions. Therefore, this study aims to find the answer against the question of what the appropriate indications are, when treating LDR with nucleoplasty.

If the width of the base of disc herniation is wider, the range to be treated must be wider. Thus, it was expected that the smaller the width, the better the clinical results. Many authors excluded subjects who had concurrent spinal stenosis from the studies.[10, 11] In the presence of spinal stenosis, because the available space in the spinal canal is even narrower than normal, it was expected that even with a small amount of herniated disc material, nerve root compression may occur more easily and strongly. There were 40 patients who had herniated disc material in the central or subarticular zone in this study. Ten of those had spinal stenosis in their treated disc level. As a cadevaric study by Troussier B et al. showed, the radiofrequency plasma effect is limited to the nucleus pulposus and it does not affect the endplate or skeletal structures.[12] Thus, it is expected that the

therapeutic effect will be limited when nucleoplasty is applied to disc herniation that is accompanied by osteophyte. The displaced disc material consists of the nucleus pulposus flowed out of the disc space, and the annulus encircling it. Han et al. conducted an experimental study which appeared to reveal that dehydration of intervertebral discs may be an important mechanism in the degeneration and stiffening of the aging spine.[13] If the leaked nucleus pulposus is physiologically stiff, the response to the radio frequency would be reduced. Vacuum disc means that there is an empty space in the intervertebral disc, and it is often observed when there are degenerative changes present in the intervertebral disc.[14, 15] It was assessed that the disc state affects the clinical outcomes after nucleoplasty. Plasma coblation is known to have a volume-reducing effect on the lumbar nucleus pulposus.[16] The reduced volume lets the intradiscal pressure decrease. However, if there is already free space in the disc even before plasma coblation is applied, decompression may be limited. However, the results have revealed that all of these factors mentioned above and the disc height and even level do not affect the clinical outcomes.

Chen et al. assessed intradiscal pressure changes after nucleoplasty in human cadavers, and analyzed the influence of degeneration on the intradiscal pressure change.[17] In this experimental study, it appeared that intradiscal pressure was markedly reduced in the younger cadavers with healthy discs as compared to the degenerative discs of the elderly. It demonstrated that nucleopalsty's intradiscal pressure-reducing effects are highly dependent on the degree of spine degeneration, and the treatment is ineffective for severely degenerated discs. Ren et al. conducted a comparative study between patients with effective and ineffective treatment after nucleoplasty.[18] Their study

demonstrated that the most important factor that can affect the efficacy of nucleoplasty was the severity of spinal degeneration. The current study also demonstrated that nucleoplasty is significantly ineffective in treating severely degenerated discs, which is consistent with the results of the studies just mentioned. Moreover, some authors have excluded patients who had evidence of severe disc degeneration from their studies.[9, 19, 20]

An interesting result of this study was that the group of patients who had extruded disc herniation obtained significantly better clinical outcomes than those having protruded disc herniation. Mirzai et al. and Adam et al. assigned that only disc herniation with a diameter of less than 6 mm be treated with nucleoplasty in their studies.[9, 21] It seems that many authors have regarded that extruded disc herniation or large disc herniation may not be good candidates for nucleoplasty. However, this study revealed the unexpected opposite result. The author theorized why this could have happened, and then focussed on the following two facts. First, considering that the essential mechanism of nucleoplasty, the plasma ablation, affects mainly the nucleus pulposus. The proportion of nucleus pulposus in the displaced material of extruded disc herniation is higher than that of the protrusion. Therefore, it could be expected that extruded disc herniation might respond better to nucleoplasty than protruded disc herniation can; therefore, the pain reduction experienced by the patient may be greater. Sim et al. also reported treating two patients with extruded cervical disc herniation, and one of them showed excellent and the other good results.[22] Although it involved cervical pathology, this report supported the conclusion that extrusion type disc could be a good indication for nucleoplasty. The author also re-examined the technical method for a possible explanation. In order to remove the

extruded disc material that has penetrated deep into the spinal canal, the probe has to enter the canal as deeply as possible, but everyone knows that there is a risk of thermal damage against the neural tissue. The operator, who is also the author, tried to remove the disc material in the spinal canal as much as possible without thermal damage. To that effect, the operator used the Stepping back technique in all cases (Fig. 3). Perhaps this may have contributed to maximize elimination of the extruded disc material placed deeply in the spinal canal. There was no single case of thermal damage among the patients included in this study. However, the better results for the extrusion type was not seen on the patient satisfaction outcome, but only on the post-operative pain reduction. This study did not demonstrate that the patient satisfaction of extruded disc herniation was better because its statistical analysis did not show a significance. It is thought that it was caused by the small number of patients with extruded discs. So, another study with a bigger sample size is needed to obtain statistical support with strong evidence.

As a result of randomly performing the procedure without considering various anatomical factors, the mean improvement of pain in all patients included in this study was 39.5%. This value is relatively low, when compared to the usual results of microscopic discectomy. However, when analyzing the clinical outcomes only in patients with extruded disc herniation, and who had disc degeneration of Pfirrmann grade II or III, the mean NRS reduction rate of radicular pain was 67.9% and six out of total eight patients answered “excellent” regarding satisfaction on the MacNab criteria. This reiterates that we have to choose the indication carefully.

The limitations of this study are the small number of patients, the short term of follow-up periods, and its retrospective origin.

V. Conclusion

Nucleoplasty could be effective treatment for LDR in certain anatomical conditions under careful selection of patients. The most important factor is that LDR with severe degenerative disc changes, i.e. those above Pfirrmann Grade III, must be excluded from the candidates. Contrary to popular belief, extruded disc herniation is thought to be within the range of indications for nucleoplasty, if effective techniques are applied.

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Table 1 Patient demographics		
Gender(n (%))	Male	33 (57.9)
	Female	24 (42.1)
Age(years)	Mean ± SD	55.9 ± 15.1
	Range	20 - 81
Duration of pain(months)	Mean ± SD	8.2 ± 13.9
	Range	0.3 - 60
Follow-up period(months)	Mean ± SD	9.4 ± 4.3
	Range	3 - 18

Table 2 Anatomical factors and correlations with clinical outcomes

Anatomical factors	Value		Mean NRS reduction(%)	MacNab criteria[1]	
				nsatisfied(n	Satisfied(n)
Level of disc(n (%))	L2-3	1 (1.8)	39.5	1	0
	L3-4	7 (12.3)	34.5	5	2
	L4-5	30 (52.6)	25.1	14	16
	L5-S1	19 (33.3)	32.6	11	8
			p=0.725	p=0.479	
	L2-5	38 (66.7)	42.8	20	18
	L5-S1	19 (33.3)	33	11	8
			p=0.241	p=0.844	
Width of disc herniation(n (%))	Single zone	23 (40.4)	37.7	11	12
	Multiple zone	34 (59.6)	40.7	20	14
			p=0.73	p=0.413	
Shape of displaced disc(n (%))	Protrusion	48 (84.2)	34.3	29	19
	Extrusion	9 (15.8)	67.3	2	7
			p=0.009*	p=0.065	
Pre-existing spinal stenosis(n (%))[3]	Present	10(25)	41.8	5	5
	Absent	30 (75)	38.8	17	13
			p=0.776	p=0.731	
Accompanying osteophyte(n (%))	Present	16 (28.1)	32.9	20	21
	Absent	41 (71.9)	42.1	11	5
			p=0.398	p=0.174	
Disc height(mm)	Mean±SD	2.2±1.1	r=0.022	r=0.29	
	Range	0.4 - 5.1	p=0.871	p=0.831	
Degree of disc degeneration(n (%))[2]	II or III	42 (73.7)	54.9	19	23
	IV or V	15 (26.3)	21.7	12	3
			p=0.016*	p=0.02*	
Physiologic appearance of displaced material in MRI(n (%))	Stiff	13 (22.8)	32.2	9	4
	Soft	44 (77.2)	41.7	22	22
			p=0.425	p=0.221	
Vacuum disc(n (%))	Present	12 (21.1)	32.9	8	4
	Absent	45 (78.9)	14.3	23	22
			p=0.464	p=0.336	

[1] The effective means it was excellent or good, and the ineffective means it was fair or poor in MacNab criteria.

[2] Assessed with Pfirrmann grading system.

[3] Assessed only with 40 patients whose disc is herniated including central canal side.

* Statistically significant.

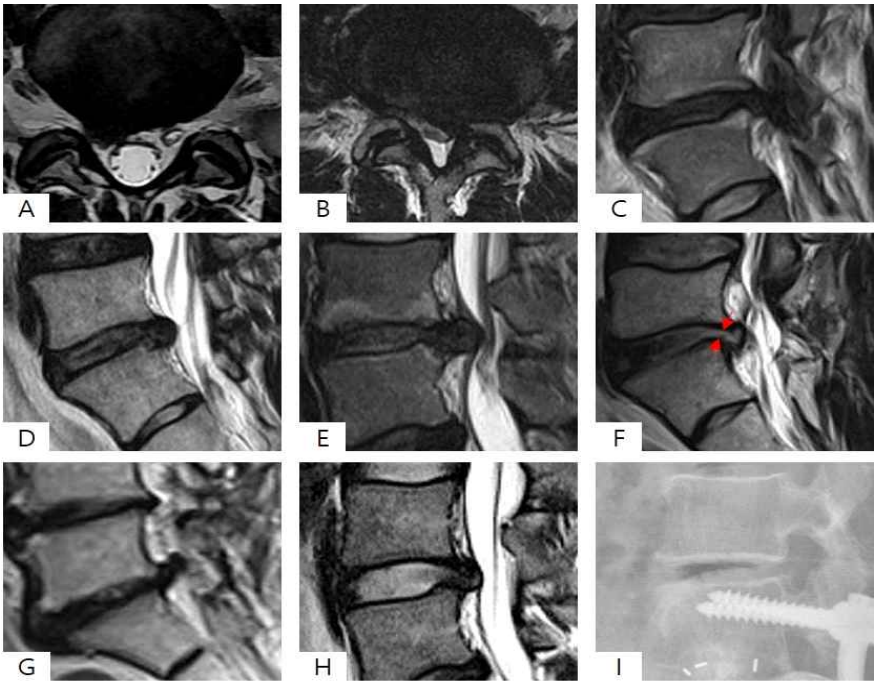

Fig 1. Illustrative images of the anatomical factors investigated in this study.

A, Single zone herniation. The width of disc herniation is localized only at right paracentral zone. **B**, Multiple zone herniation. The width of disc herniation is at central to left foraminal zone broadly. **C**, Disc herniation is accompanied with osteophyte. **D**, Protrusion type disc herniation. **E**, The greatest diameter of the displaced disc material is larger than the base at the disc space of origin. Extrusion type disc herniation. **F**, Disc height is measured with the smallest gap between the top and bottom endplate of the approaching pathway to the target disc herniation site. **G**, Herniated disc shows hypointense, and seems dark and dry on T2WI of MRI. Stiff disc herniation. **H**, Herniated disc shows isointense, bright, and relatively rich in water content. Soft disc herniation. **I**, Intradiscal empty space. Vacuum disc.

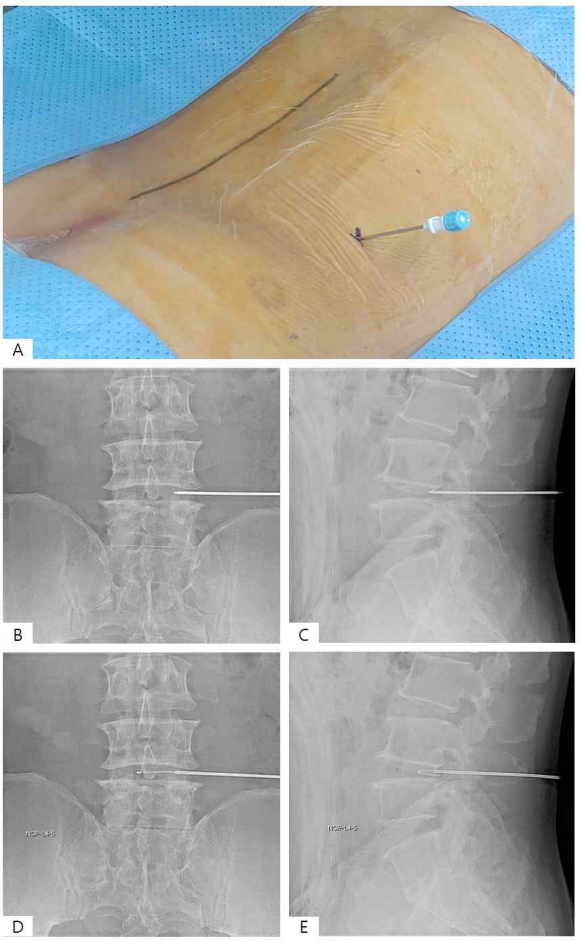

Fig 2. Sequential process from skin entry of introducer needle for approaching of the radio frequency probe.

A, Skin entry was made at 10-12cm lateral from midline. **B, C**, Introducer needle was inserted into the disc space under fluoroscopic guidance. The tip of the needle passed through the annulus fibrosus and was placed in the space of nucleus pulposus. **D, E**, The YES DISC® (Mcare, Seongnam-si, Gyeonggi-do, South Korea) was delivered into the disc space through the introducer needle and the radio frequency probe was approached to the target under the fluoroscopic guidance.

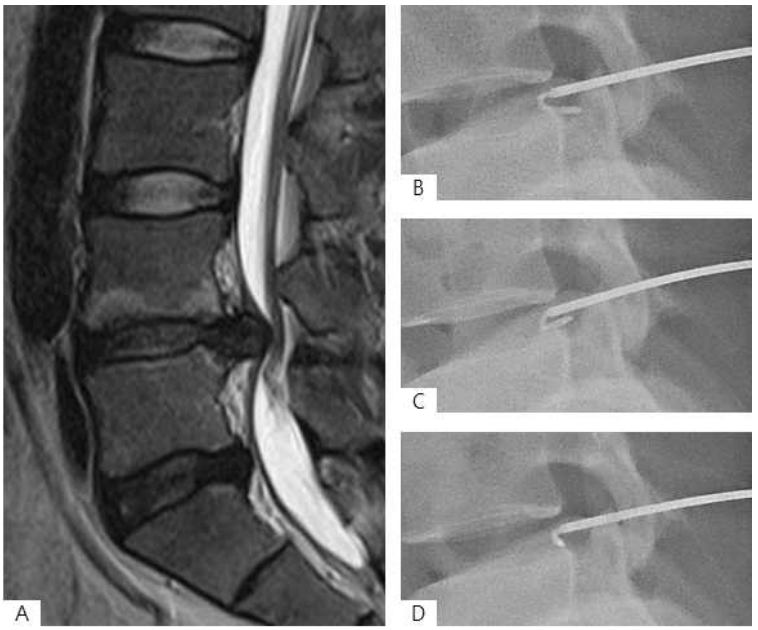

Fig 3. The Stepping back technique to remove extruded nucleus pulposus as much as possible without thermal damage against neural tissue

A, An illustrative image of sagittal plane T2WI of lumbar spine MRI shows an extrusion type disc herniation filled with nucleus pulposus. The greatest diameter of disc material is larger than the base at the disc space of origin and it advances more than the half of the sagittal diameter of spinal canal.
B, The radio frequency probe is placed deeply into the extruded disc material in spinal canal. Then, the plasma coblation is applied through the tip of the probe and the probe is advanced carefully and slowly until the patients start to complain burning sense on their leg. If the disc material diminish in size and the nerve root comes closer to the probe or heat from the probe is conducted to the nerve root, the patients feel burning sense on their leg.
C, As soon as the patients complain, the plasma coblation is stopped immediately. And the probe is slightly pulled back, then the plasma

coblation is reapplied until the patients complain again. This process is repeated until the probe gets back into the disc space.

D, The plasma coblation is also applied to the nucleus pulposus in the disc space in order to decrease intradiscal pressure and prevent recurrent herniation.